



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/446,681 03/14/00 ARCHER

J

EXAMINER

000110 HM12/0913
DANN DORFMAN HERRELL & SKILLMAN
SUITE 720
1601 MARKET STREET
PHILADELPHIA PA 19103-2307

SANDALS III

ART UNIT

PAPER NUMBER

1636

DATE MAILED:

09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/446,681

Applicant(s)

Archer et al.

Examiner
William Sandals

Art Unit
1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 14, 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Art Unit: 1636

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Claims 1-24 have been designated as Groups I and II. Claims 26-30 and 32-39 have been designated as groups IV-XI and XIII-XIV. The claims of these groups comprise multiple inventions which are unique combinations of multiple different special technical features.

Group I, claim(s) 1-24, drawn to a method for identifying an inducible promoter DNA from bacterial DNA encoding a mycolic acid gene.

Group II, claim(s) 1-24, drawn to a method for identifying DNA from bacterial DNA encoding a mycolic acid protein.

Group III, claim(s) 25, 46 drawn to a method of producing a modified inducible promoter from bacterial DNA encoding a mycolic acid gene.

Group IV, claim(s) 26-30, 32-37, 48 drawn to an isolated nucleic acid comprising an inducible promoter from bacterial DNA encoding a mycolic acid gene.

Art Unit: 1636

Group V, claim(s) 26-30, 32-37, 48 drawn to an isolated nucleic acid comprising a DNA from bacterial DNA encoding mycolic acid protein *R. corallina* ohp.

Group VI, claim(s) 26-30, 32-37, 48 drawn to an isolated nucleic acid comprising a DNA from bacterial DNA encoding mycolic acid protein Regulator, REG.

Group VII, claim(s) 26-30, 32-37, 48 drawn to an isolated nucleic acid comprising a DNA from bacterial DNA encoding mycolic acid protein Transport, TRANS.

Group VIII, claim(s) 26-30, 32-37, 48 drawn to an isolated nucleic acid comprising a DNA from bacterial DNA encoding mycolic acid protein Monooxygenase, MONO.

Group IX, claim(s) 26-30, 32-37, 48 drawn to an isolated nucleic acid comprising a DNA from bacterial DNA encoding mycolic acid protein Hydroxymuconic semialdehyde hydrolase, HMSH.

Group X, claim(s) 26-30, 32-37, 48 drawn to an isolated nucleic acid comprising a DNA from bacterial DNA encoding mycolic acid protein Alcohol dehydrogenase, ADH.

Group XI, claim(s) 26-30, 32-37, 48 drawn to an isolated nucleic acid comprising a DNA from bacterial DNA encoding mycolic acid protein Catechol 2, 3-dioxygenase, CDO.

Group XII, claim(s) 31, 47 drawn to a nucleic acid which effects site specific integration of a heterologous signal gene into the genome of a host cell such that it is operably linked to an inducible promoter.

Group XIII, claim(s) 26, 30, 32, 35, 38-39, drawn to a biosensor host and a method of transforming.

Art Unit: 1636

Group XIV, claim(s) 26, 30, 32, 39, 40-43, 49 drawn to a method of detecting analyte in a sample.

Group XV, claim(s) 44 and 45, drawn to a kit for detecting analyte in a sample.

2. The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The method of Group I comprises screening a host cell for an inducible promoter which is not present in the other groups. The method of Group II comprises screening a host cell for DNA encoding proteins which is not present in the other groups. The method of Group III comprises producing a modified inducible promoter which is not present in the other groups. The isolated nucleic acids of Group IV-XII comprises nucleic acids encoding proteins, each of which is completely unrelated biologically, chemically, physically and structurally to each of the other groups. The biosensor and method of Group XIII comprises a biosensor and method of transforming which is not present in the other groups. The method of Group XIV comprises a method of detection of an analyte which is not found in the other groups. The kit of Group XV comprises a biosensor and one or more further materials for a method of detecting an analyte in a sample which is not present in the other groups.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1636

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Conclusion

5. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Friday from 8:30 AM to 5:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Schwartzman can be reached at (703) 308-7307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.
Examiner
September 9, 2001


TERRY MCKELVEY
PRIMARY EXAMINER